Citation:

Mennella JA. Regulation of milk intake after exposure to alcohol in mothers' milk. *Alcohol Clin Exp Res*. 2001; 25 (4): 590-593.

PubMed ID: 11329500

Study Design:

Non-randomized crossover trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine if infants would compensate for the diminished milk intake that occurs after alcohol exposure in breast milk, if the mothers then refrained from drinking alcohol the following 16 hours.

Inclusion Criteria:

- Lactating women
- Non-smoking
- Exclusively breastfeeding their infants
- Had consumed at least one alcoholic beverage during lactation
- Healthy infants
- Informed consent was obtained.

Exclusion Criteria:

- Men and non-lactating women
- Women who were not exclusively breastfeeding their infants
- Women who smoke
- Unhealthy infants.

Description of Study Protocol:

Recruitment

- Recruited from ads in local newspapers
- Also recruited from Women, Infant and Children (WIC) centers throughout Philadelphia.

Design

- Non-randomized trial
- Within-subject design.

Intervention

- Women were given an alcoholic drink and then their infants were monitored for 16 hours
  - Ethanol (0.3g per kg of body weight) as 15% solution (vol/vol) in orange juice
  - Control beverage was plain orange juice of an equal volume
  - Beverage was consumed within 15 minutes.

Statistical Analysis

- Repeated Measures Analyses of Variance (ANOVA) was calculated to determine whether there were significant differences in the amount of milk consumed as a function of time since exposure in four-hour blocks (zero to four, four to eight, eight to 12 and 12-16 post-exposure)
- Significant effects in the ANOVA were probed by paired T-tests
- Chi square analyses were performed to determine if there were significant differences in the mothers' perception of their lactation performance or infants' behaviors on the two test days
- Summary statistics reported as means ± SEM
- P-values represent two-tailed tests
- Yates' correction for continuity was applied to all chi square analyses.

Data Collection Summary:

Timing of Measurements

- Each mother-infant pair was tested on two days, separated by one week
- Mother and infants arrived at 9:30 a.m., having last fed their infants at similar time on each test day
- Mothers drank either the control or the drink containing alcohol in counterbalanced order
- Beverage was consumed within 15 minutes
- For the next four hours the infants were videotaped as they breastfed on demand
- Immediately before and after each feed the infant was weighed
- After the feeding, the mothers were asked if they noticed a changed in the infant's behavior, whether they thought their infants got enough milk and whether they experienced a let-down
- The mother and infant returned home and for at least the next 16 hours, the mother weighed the infant before and after each breastfeed.

Dependent Variables

- Volume of milk intake
  - The infant's weight was measured on an Acme Medical Pediatric Scale, accurate to 1.0g
  - The same type of scale was used at the testing center and at home
  - The scale was delivered to the mothers' home several days before testing and the mothers were trained on it's use
  - Mothers completed the weighing exercise several times at home and then again at the testing center until it was consistently performed properly
  - The milk volume was estimated by dividing the weight of the milk consumed (the

change in the infant's weight) by 1.031, the specific gravity of mature human milk
- Number of breastfeeds
  - For the first four hours after the intervention, the infants were videotaped as they breastfeed and the frequency documented
  - Once they returned home, the mothers documented the time of feedings and from which breast the infant fed
  - Phone contact was made with the mother to measure compliance.

Independent Variables

- Alcohol consumption
  - Ethanol (0.3g per kg of body weight) as 15% solution (vol/vol) in orange juice
  - Control beverage was plain orange juice of an equal volume
  - Beverage was consumed within 15 minutes
  - Mothers were instructed to refrain from drinking any alcoholic beverages during the three days preceding and the two days after each test day.

Control Variables

Maternal perceptions: Mothers were asked immediately after feeding if they noticed a change in the infant's behavior, whether they thought their infants got enough milk and whether they experienced a let-down.

Description of Actual Data Sample:

- *Initial N:* 15 mother-infant pairs
- *Attrition (final N):*
  - 12 mother-infant pairs
  - Infants: Eight girls, four boys
- *Age:*
  - Mothers average: 27.8±1.2 years
  - Infants: 1.8 to five months (mean=3.1±0.3 months)
- *Ethnicity:* 10 Caucasian; Two African American
- *Other relevant demographics:* 58.3% multiparous
- *Anthropometrics:* Infants' weights and lengths fell within the 10th and 95th percentile of published growth standards
- *Location:* Philadelphia, Pennsylvania.

Summary of Results:

Key Findings

- Infants consumed significantly less breast milk during the first four hours after the mothers consumed the ethanol drink
  - Approximately 20% less
  - P=0.04
- Infants breastfed a similar number of times (P=1.00) during the first four hours after the mothers consumed the ethanol drink
- Infants compensated for the diminished intake during the eight to 12 hours following

exposure
- P=0.05
- Increased number of breastfeedings occurred during this period (P=0.04).

Other Findings

Mothers' drinking during pregnancy and lactation

- All reported drinking very little during pregnancy
  - Range zero to four alcoholic beverages per month
  - Mean=1.2±0.3 drinks per month
- Significant increase of drinking during lactation
  - Mean=7.2±1.9 alcoholic beverages per month (paired T(11df)= -3.39; P=0.006)
  - Range less than one to 20 drinks per month.

Advice on drinking during lactation

- 41.7% reported that they were advised to drink alcohol during lactation by a health professional (doctor, lactation consultant, midwife, nurse)
- 16.6% were discouraged from drinking
- 41.7% were not given any advice at all about drinking.

Type of Beverage Consumed by Lactating Mothers			
Behavior: Hours Past Exposure	**Orange Juice Alone (Control)**	**Orange Juice Plus Ethanol (ROH)**	**Percent Difference [a] (ROH-Control)/Control*100)**
Milk intake (ml)			
Zero to four	200.6±24.4	147.4±17.7*	-21.1±8.3
Four to eight	138.7±18.1	120.2±18.9	13.3±28.3
Eight to 12	117.8±16.7	149.1±17.4*	38±16.1
12 to 16	70.8±16.7	77.6±13.3	24.7±34.7
Total	527.8±37.7	494.3±46.9	-7.3±6.4
Number of breastfeeds			
Zero to four	2.4±0.2	2.4±0.3	5.5±14.9
Four to eight	2.3±0.3	2.0±0.2	6.9±20.3
Eight to 12	1.5±0.2	2.1±0.3*	45.8±19.9
12 to 16	1.4±0.3	1.3±0.1	8.3±17.3
Total	7.6±0.6	7.8±0.7	6.3±10.3

[a]Percent difference scores were calculated from each infant's individual data, not from the group means

*P<0.05 when compared to the control condition.

Mothers' perceptions

- Mothers' reported that they experienced a letdown during nursing, not significant between intervention and control (x^2=0.21, 1*df*, P not significant)
- No difference in the infants' behaviors (x^2=0.07, 1*df*, P not significant)
- Mothers' believed that their infants had consumed enough milk (x^2=0.06, 1*df*, P not significant).

Maternal beliefs and infants' responses

- ANOVA was conducted to determine whether there were differences between infants whose mothers were encouraged to drink alcohol during lactation (N=5) vs. those mothers who received no advice at all (N=5)
- No significant effects for any of the measures studied
  - Milk intake $F(1,8df)$=0.24, P=0.64
  - Number of feeds: $F(1,8df)$=0.02, P=0.88
- No significant interaction effects between these two groups and experimental conditions or time since exposure (all P-values>0.10).

Author Conclusion:

The study indicated that infants' intake of breast milk is diminished (approximately 20% decrease) in the short-term after exposure to alcohol in the mothers' milk. Infants compensated for this decrease when the mothers refrained from alcohol for the next eight to 12 hours.

Reviewer Comments:

The authors did not mention if the mothers were able to distinguish the alcoholic drink from the control, or any possible effect that might have had on the results.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes

4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	No

4.1.	Were follow-up methods described and the same for all groups?	No
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A

7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes